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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR NOPH/127/JGK 6465 10/747,827 12/29/2003 David Houze **EXAMINER** 7590 06/07/2005 Noven Pharmaceuticals, Inc. GEHMAN, BRYON P Jay G. Kolman, Esq. ART UNIT PAPER NUMBER 11960 S.W. 144 Street Miami, FL 33186 3728

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/747,827	HOUZE, DAVID
	Examiner	Art Unit
	Bryon P. Gehman	3728
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on 13 A	pril 2005.	
<u> </u>	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) <u>2-18</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>2-18</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:		
1. ☐ Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No.		
3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail D 5) Notice of Informal F	ate Patent Application (PTO-152)
Paper No(s)/Mail Date <u>8/20/04</u> .	6) Other:	
U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office A	ction Summary Pa	art of Paper No./Mail Date 20050606

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1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

- 2. The abstract of the disclosure is objected to because in line 3, "retention means" is improper. Correction is required. See MPEP § 608.01(b).
- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 2-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, line 4, "a product" is indefinite, as a product per se has already been positively defined. See also claim 4, line 2. In lines 11, 14 and 16, "the product package material" lacks antecedent basis or is inconsistent with line 3, "product packaging material".

In claim 5, line 5, "ethylense(sic)/vinyl" and "ethylene/ethyl" are indefinite as to the meaning of the slashes. See also claim 15.

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In claim 7, "the product" is not seen as being opened.

In claim 8, "the retention means" lacks antecedent basis for only one.

In claim 13, line 3, "the second edge" lacks antecedent basis.

In claim 14, line 2, "being sealed...receiving a product" is redundant and confusing, its elimination being more accurate. In line 3, "the inner layer" lacks antecedent basis.

In claim 15, lines 1-2, "the inner product packaging layer" lacks antecedent basis as a term. See also claim 17, line 2.

In claim 16, line 2, "the inner packaging layer" lacks antecedent basis as a term.

In claim 17, lines 1-2, "the retention means" (singular) lacks antecedent basis.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
- 6. Claims 2-5, 7-9, 12-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Salfisberg (2,325,021). Claims 2-5, 7-9, 12-13 and 18 are rejected under

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35 U.S.C. 102(b) as being anticipated by Schneider (2,976,988). Claims 2-9, 12-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by LeBlanc (3,155,282). Claims 2-7, 9-10, 12-13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelsen (3,199,437). Claims 2-5, 7-9, 12-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tigner (3,550,764). Claims 2-6 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Zamarra (3,613,680). Claims 2-5, 7, 9, 12, 14-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Truluck (6,227,359). Claims 2-5, 7-9, 12 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Tu et al. (2003/0152300). Claims 2-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Shudo et al. (2004/0159575). Each discloses a product retention package having an internal cavity (3 or 19; 20 or 21; between 10 and 11; inside 10; inside 10; inside A; between 18 and 20; 131 or 331; between 6 and 8; respectively) in which a product (x, 20 or 21; T; 12; 22; 16; 7; 14; described articles; 4) is positioned, comprising a layer (5 or 22; at 15; 10 or 11; forming the tube; 12 or 14; 1 and 2; 18 or 20; 11 or 12; 22-34) sealed to form the cavity, at least one retention means (4 or 9; 18 or triangular seal at 25; 14 or 21; 26, 26; 30; 8; 52; at 142 and 342; 16) to restrict movement of the product to maintain the product distal to the opening location (6 or 23; 25; 15-15; 16; 34 and 36; 6; at 24; 16 intersecting 132 or 36 intersecting 332; above seal 16) of the package, the retention means being one of a sealed portion extending from the periphery, one or more sealed portions separate from the periphery. and one or more openings sealed along their periphery internal of the periphery of the cavity.

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As to claims 3-5, each discloses one of the recited alternatives of sealing and material, and the packaging material sealing to itself and one of the layers.

As to claim 6, LeBlanc, Nelsen and Shudo et al. suggest opaque material as an alternative.

As to claim 7, each discloses visual means (structure) that identify visually the location of intended opening of the package.

As to claim 8, all but Nelsen, Zamarra and Truluck locate the retention means at the opening location.

As to claim 9, all but Zamarra disclose a mechanical means (8; 27; 15-15; 16; 30 or 34-36; 60; 15-16; scissors or other cutting implement) to open the package.

As to claim 10, Nelsen and Shudo et al. disclose cutting with mechanical means (column 2, lines 63-66; section 0029).

As to claim 11, Shudo et al. disclose a transdermal delivery system.

As to claim 12, all but Zamarra disclose the package sealed along the entire periphery.

As to claim 13, all but Zamarra, Truluck and Tu et al. disclose the opening location extending from one edge to another.

As to claims 14-15 and 17, Tigner, Truluck and Shudo et al. disclose multiple layers of the packaging material with the retention means between the inner and outer layers.

As to claim 16, Shudo et al. discloses an adhesive layer (34).

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As to claim 18, since each requires an opening facilitator or in Zamarra is not torn, each is inherently somewhat tear resistant.

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of the previously employed references in view of Shudo et al.. The claimed product package is discrete from a cutting tool. Shudo et al. disclose opening a package employing a cutting tool (section 0029). To employ a discrete cutting tool to open the package of any one of the prior art would have been obvious in view of Shudo et al. to facilitate opening, as suggested by Shudo et al.. Since the cutting tool is not part of the claimed package, its existence extraneous to the package fails to further distinguish the claimed package itself. Shudo et al. disclose a package for a transdermal delivery system. To modify the structure of Shudo et al. employing the structure of any one of the base references described above would have been obvious in order to facilitate opening of the package without interference from the system.
- 9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shudo et al. as applied to claim 2 above, and further in view of either Zamarra or Truluck. To

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employ the retention means of either one of Zamarra or Truluck to modify the package of Shudo et al. would have been obvious in order to locate the content in a particular protected location.

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- 10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Tigner or Truluck as applied to claim 14 above, and further in view of Shudo et al.. Shudo et al. disclose employing adhesive (34) to join layers of a laminate. To modify the laminate of Tigner or Truluck employing adhesive to join the layers would fail to provide any new and unexpected result in view of Shudo et al., as it was previously known to join laminate layers employing adhesive.
- 11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not seen how the claimed mechanical means comprise part of the claimed product package, as each would discrete therefrom.

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13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shown are cartons with a severable top panel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Monday through Wednesday from 5:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Day V. Isch

Bryon P. Gehman Primary Examiner Art Unit 3728

BPG